^{99m}Tc-maraciclatide Granted FDA Fast Track Designation for the Diagnosis of Superficial Peritoneal Endometriosis

London, UK, 2 July 2024. Serac Healthcare Limited, a clinical radiopharmaceutical company developing an innovative molecular imaging agent, announced today that the US Food and Drug Administration (FDA) has granted Fast Track Designation to ^{99m}Tc-maraciclatide as a diagnostic SPECT-CT agent for the visualisation and diagnosis of superficial peritoneal endometriosis in women of 16 years and older.

Fast track is a process designed to facilitate the development and expedite the review of drugs to treat (or in our case, diagnose) serious conditions and fill an unmet medical need. Criteria include improving the diagnosis of a serious condition where early diagnosis results in an improved outcome.

Endometriosis is a common inflammatory disease that affects up to one in 10 women of childbearing age, about 190 million women worldwide. Endometriosis occurs when tissue similar to the lining of the uterus is found outside the uterus, usually in the pelvis, but sometimes also elsewhere in the body (e.g. the lungs). The presence of this tissue can lead to significant pain and infertility. It can be difficult to diagnose endometriosis because the symptoms can vary considerably, and mimic those of other conditions. This leads to an average delay of 7.5 years from first symptom onset to diagnosis. Furthermore, superficial peritoneal endometriosis (SPE) is the earliest and most common form of endometriosis, comprising approximately 80% of all diagnoses. However, due to the plaque-like nature and generally small size of lesions, SPE is not well visualised with current non-invasive imaging tools (ultrasound and MRI) and definitive diagnosis requires laparoscopy.

Previously presented preliminary data from the "Detecting Endometriosis expressed integrins using technetium-99m" (DETECT) imaging study, demonstrated that ^{99m}Tc-maraciclatide correctly identified superficial peritoneal endometriosis in those who went on to have this early-stage endometriosis confirmed by laparoscopy. The ongoing Phase II study will complete later this year.

Benefits of Fast Track designation include:

- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials
- Rolling Review, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed.

All of which is intended to reduce the time to approval in the US and enable patients to benefit sooner.

David Hail, Chief Executive Officer of Serac Healthcare, said:

"Granting Fast Track designation to maraciclatide highlights the FDA's recognition of the critical need for improved diagnosis of endometriosis. The average delay for diagnosis of this condition, which affects 190 million women worldwide, is seven and a half years and is often only possible with laparoscopy. We are committed to working closely with the FDA and clinicians to complete the development of ^{99m}Tc-maraciclatide.

A non-invasive test which could be used for earlier diagnosis of endometriosis would represent a major advance in women's healthcare."

About ^{99m}Tc-maraciclatide

^{99m}Tc-maraciclatide is a radio-labelled tracer which binds with high affinity to the cell adhesion protein $\alpha_v\beta_3$ integrin and images angiogenesis (new blood vessel formation) which is known to be critical to the establishment and growth of endometriotic lesions. Clinical trials in a range of conditions, including breast cancer, bone metastases and rheumatoid arthritis, in which angiogenesis plays a key role, have shown the agent to perform as expected and be well tolerated.

-ENDS-

Maraciclatide is for investigational use only and is not approved by the FDA or UK and European regulatory authorities.

For more information, please contact:

Serac Healthcare Ltd	www.serachealthcare.com
David Hail, Chief Executive	+44 (0)20 8948 0000 info@seraclifesciences.com
Francetta Carr, Communications	+44 (0)7711 010820 francettacarr@seraclifesciences.com

Notes to Editors

About Serac Healthcare Ltd

Serac Healthcare is a clinical radiopharmaceutical company with deep expertise in discovering, developing and commercialising innovative molecular imaging technologies. Using these targeted technologies to underpin personalised medicine in the fields of endometriosis and inflammatory arthritis, Serac Healthcare is focused on bringing to market effective tools to accelerate diagnosis, and to deliver earlier and more effective treatment decisions. Serac Healthcare Ltd is a wholly owned subsidiary of Serac Life Sciences Limited.

About Fast Track designation

https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

About the DETECT study

The study is jointly sponsored by the Oxford Endometriosis CaRe Centre and the Nuffield Department of Women's and Reproductive Health, Oxford University, and funded by Serac Healthcare Ltd who are providing the experimental imaging marker ^{99m}Tc-maraciclatide. Further details are available on ClinicalTrials.gov here.